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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,571	03/03/2004	Neil T Dear	ABB10010P0630US	9704
32116 7590 06/01/2007 WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. MADISON STREET SUITE 3800 CHICAGO, IL 60661			EXAMINER SWOPE, SHERIDAN	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/009,571	DEAR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12-12-2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Applicant's response on April 16, 2007, to the Final Rejection of this case mailed January 12, 2007, is acknowledged. It is acknowledged that no claims have been cancelled, amended, or added. Claims 1-6 are pending. Claim 6 was previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-5 are hereby reconsidered.

#### ***Drawings***

Objection to Figure 1 for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO: ) is maintained; corrections have not been made.

#### ***Specification-Objections***

Objection to the specification for improper formatting is maintained; corrections have not been made.

Objection to the specification for containing hyperlinks is maintained; corrections have not been made.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

#### ***Utility***

Rejection of Claims 1-5 under 35 U.S.C. 101/112 because the claimed invention lacks patentable utility, for the reasons set forth in the prior actions, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

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(A) The application leaves no doubt that the CAPN11 sequence is expressed most strongly in testis (Fig 3).

(B) It is also established that CAPN11 is involved in processes like germ cell apoptosis or regulation of testis-specific transcription factors (pg 3).

(C) CAPN11 can be used as a bait for identifying inhibitors, which can be used for treatment of disorders associated with elevated CAPN11 activity, such as infertility in men (pg 4).

(D) Ben-Aharon et al, 2006 clarifies that the expression of CAPN11 during spermatogenesis and its localization in spermatozoa suggest that it is involved in regulating calcium-dependent signal transduction during meiosis and sperm functional processes.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: This is the identical argument Applicants' presented in their response of November 13, 2006. Applicants are referred by to Reply (A) provided in the action mailed January 12, 2007. In brief, RNA encoding the protein of SEQ ID NO: 2 is not specific for testis, since it is also expressed in other tissues, including mammary gland and thymus (Fig 3; D8).

(B) Reply: This is the identical argument Applicants' presented in their response of November 13, 2006. Applicants are referred by to Reply (B) provided in the action mailed January 12, 2007. In brief, a statement of what CAPN11 might be involved in is not a disclosure of what cellular or biochemical processes or diseases CAPN11 is involved in and does not provide a specific and substantial utility.

(C) Reply: This is the identical argument Applicants' presented in their response of November 13, 2006. Applicants are referred by to Reply (C) provided in the action mailed

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January 12, 2007. In brief, the protein of SEQ ID NO: 2 cannot be used for identifying inhibitors because an assay for measuring activity has not been provided. Moreover, the specification fails to teach the skilled artisan how to use any inhibitor of CAPN11 activity to treat or diagnose any specific diseases or disorders. Mere assertion that inhibitors of CAPN11 activity can be used to treat infertility does not provide a patentable utility for the protein of SEQ ID NO: 2.

(D) Reply: This is the identical argument Applicants' presented in their response of November 13, 2006. Applicants are referred by to Reply (D) provided in the action mailed January 12, 2007. In brief, Ben-Aharon's statement that the expression and localization of calpain 11 suggests that calpain 11 is "involved" in the general process of meiosis or any function of the sperm is not a disclosure of a specific and substantial function for CAPN11. Moreover, the purpose of citing Ben-Aharon et al in the prior action is to point out that as recently as 2006 the substrates and function of calpain-11 were yet to be determined (Ben-Aharon et al, 2006; pg 772, parag 4).

### **Written Description**

Rejection of Claims 4 and 5 under 35 U.S.C. 112, first paragraph/written description, as described in the prior actions, is maintained.

In support of their request that said rejection be withdrawn, Applicants argue that the specification, at page 4, clearly discloses that CAPN11 is a calcium-dependent protease. This is the identical argument Applicants' presented in their response of November 13, 2006.

Applicants are referred by to the Office's reply provided in the action mailed January 12, 2007.

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In brief, mere assertion that the protein of SEQ ID NO: 2 has homology to chicken  $\mu$ /m calpain, is not a disclosure of a method for identifying inhibitor for the protein of SEQ ID NO: 2.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

#### **Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.  
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SHERIDAN SWOPE, PH.D.  
PRIMARY EXAMINER